K083769
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510(k) Summary of Safety and Effectiveness

JAN 14 2009

Manufacturer Name:	EastMed Inc.
Contact Name:	Karen Farrell
Title:	VP, Regulatory Affairs & Health Education
Postal Address:	1721 Lower Water Street Suite 301 Halifax, Nova Scotia B3J 1S5
Phone Number:	902-421-5692
Fax:	902-421-5695
Date:	December 17, 2008

Device Proprietary Name:	uresta™ Pessary
Device Common or Usual Name:	Vaginal Pessary
Classification Name:	Pessary, Vaginal
Classification Code	HHW
Classification Panel	General Hospital
Regulation Number	884.3575

Predicate Device:

Substantial equivalence is claimed to the following devices:

- uresta™ Pessary, K081385, EastMed Inc.
- Instead Softcup – Feminine Protection Cup, K971303, Ultrafem Inc.

Description of the Device

The uresta™ Pessary has been modified to be manufactured using an alternate non-latex thermoplastic elastomer rubber. No other changes have been made to the device.

Intended Use of the Device

The uresta™ Pessary is designed for adult women who experience involuntary urine loss from the most common type of incontinence; stress incontinence, from physical activity such as coughing, laughing and/or exercising.

Performance

EastMed Inc. has undertaken biocompatibility testing to support the safety of the new material.

Substantial Equivalence

Conclusion

Based on the information provided in this 510(k) premarket notification, the modified uresta™ Pessary is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2009

EastMed, Inc.
c/o Ms. Roshana Ahmed
Manager, Regulatory Affairs (Devices)
CanReg, Inc.
4 Innovation Drive
Dundas, Ontario
CANADA L9H 7P3

Re: K083769
Trade/Device Name: uresta™ Pessary
Regulation Number: 21 CFR §884.3575
Regulation Name: Vaginal pessary
Regulatory Class: II
Product Code: HHW
Dated: December 17, 2008
Received: December 18, 2008

Dear Ms. Ahmed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statment

510(k) Number: K083769

Device Name: uresta™ Pessary

Indication for Use: This device is for use in adult women, over 18 years of age, who experience involuntary urine loss with physical activity (stress urinary incontinence).

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation

510(k)_____

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083769